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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,590	07/20/2001	Jack V. Smith		1405

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/910,590	<b>Applicant(s)</b> SMITH, JACK V.	
	<b>Examiner</b> Bao-Thuy L. Nguyen	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 11-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/20/01</u> | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of claims 7-10 in the reply filed on July 01, 2004 is acknowledged.
2. Claims 1-6 and 11-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 01, 2004.

### *Claim Rejections - 35 USC § 112*

3. Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 contains the trademark/trade name URINE LUCK™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the adulterant being detected and, accordingly, it is unclear exact what compound is being detected since URINE LUCK™ apparently contain several different components.

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Claim 7 is confusing because it is unclear if the samples of unknown urine and calibrators are disposed in the same sampling cups, i.e. mixed together. Specifically, the recitation of a "reaction mixture composed of reagents and test samples to include unknown specimens and calibrator" renders the claim confusing.

Claims 8-10, the recitation of "can be" is vague since this is not a positive recitation that the indicator is selected from the group consisting of the recited reagents, etc.

### *Double Patenting*

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 7-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 10/394,078. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to a method for the detection of an adulterant in a urine sample using an automated analyzer and a reagent composition comprising an indicator such as 1, 2, 3, 4-tetrahydrobenzo(h)quinolone and a buffer such as citrate.

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The instant claims differ from those of '078 because it does not teach the detection of bromine, however, URINE LUCK™ has several constituents, one of which is a bromine compound, therefore, the instant claims is obvious over those of '078.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anne et al (US 6,503,726) in view of Yamashita et al (US 4,158,545).

Anne discloses a method for detecting an oxidant adulterants such as Urine Luck™ in a urine sample using a reagent solution comprising a substrate indicator and a buffer. The substrate is 3,3'-5,5'-tetramethylbenzidine (TMB), and the buffer is citrate buffer. See column 2, lines 1-11, and lines 40-62; and column 4, lines 45 through column 5, line 3. Anne teaches that the test sample may be monitored by a clinical analyzer set at a specified wavelength. See column 2, lines 21-24.

Anne differs from the instant invention in failing to teach the specific steps of the automated assay.

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Yamashita discloses an automatic chemical analyzing method and apparatus in which a plurality of samples each added with a reagent are transported through a reaction line and subjected to a reaction for optical measurement using appropriate wavelengths. See Abstract. Yamashita teaches placing test samples and calibrators as well as blanks in samples tubes. Transferring aliquots of each into reaction tubes, adding an amount of reagents into each tube and photometrically measure the reaction in each tube. See column 3, lines 40-47; column 4, lines 9-40; column 5, lines 1-32 and column 7, lines 13-24.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to automate the method taught by Anne using the automatic analyzer taught by Yamashita because Anne teaches that their method may be adapted for a clinical analyzer and Yamashita discloses such an analyzer as being well known and conventional in the art. Furthermore, a skilled artisan would have had a reasonable expectation of success in automating the method taught by Anne using the analyzer of Yamashita since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art.

### *Conclusion*

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2003/0027350

US 2003/0138959

US 5,051,238

US 5,753,451

US 5,434,083

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US 5,801,060


Wu et al., Adulteration of Urine by Urine Luck™. Clinical Chemistry. Vol. 45, No. 7, pages 1051-1057. 1999.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
8/30/04